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FACULTY OF LAW, UNIVERSITY OF MALAYA

CELEST

CENTRE FOR LAW AND ETHICS IN SCIENCE AND TECHNOLOGY





Welcome to Our Inaugural Newsletter!

The Centre for Law and Ethics in Science and Technology (CELEST) is a research centre at the Faculty of Law, University of Malaya. CELEST was previously known as the Centre of Excellence for Biodiversity Law (CEBLAW). This renaming initiative, which took place in 2017, was prompted by the transformative impact of rapid developments in science and technology on our daily lives and, more generally, the world around us. CELEST engages in and promotes research on the legal and ethical implications of the broad field of science and technology.

Given the revolutionary technological changes that are taking place, it is crucial to understand how science and technology interact with and challenge the norms and standards which we are all too familiar with. The areas of research which CELEST is interested in includes biodiversity law, cyberlaw, data protection law, energy law, environmental law, law of the sea, media law, health law and nanotechnology law.

On a wider front, CELEST is keen to explore and better understand the emerging issues that arise from the intersection between law and ethics with science and technology. In this regard, CELEST welcomes research collaborations in these fields to further the discourse between the developments in science and technology and the law as well as ethics.

CELEST is proud to present this inaugural newsletter to introduce the Centre. We hope this newsletter will encourage discussion on contemporary issues on the integration of law and ethics with science and technology. In this issue, we bring to you a brief write-up of a research currently undertaken by our researcher and academic staff at the Faculty of Law, Dr Mohammad Firdaus Abdul Aziz, which discusses ethical, legal and governance issues of biobanking.

We hope that you will enjoy reading it!

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Malaysian biobanks: is the current governance framework adequate?

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What is Biobanking?

'Biobanking', also known as 'biorepositories' and 'genetic databases', is widely regarded as an important means to facilitate biomedical research. It functions as repositories of human biological samples. The Council of Europe has offered a definition of 'biobanking' as: "the collection of biological materials which has a population basis; it is established to supply biological materials or data for multiple future research projects, contains biological materials and associated personal data that may include or may be linked to genealogical, medical and lifestyle data; it may be regularly updated and receives and supplies materials in an organized manner."

In general, there are two types of biobanks, categorised based on the purpose of its establishment and the types of samples collected namely (i) disease-specific-based biobanks that collect specific samples from patients who have specific medical conditions and (ii) population-based biobanks that collect different types of samples from large numbers of people with or without medical conditions.

Researchers would be able to use the deposited samples to carry out biomedical research on various human health issues and diseases. Such research is crucial to help patients with rare diseases whose medical needs are unmet by today's medicine and to address widely spread diseases. It could also contribute towards the discovery of new genes that are responsible for genetic diseases, which means this could even lead to medical care and treatment tailored specifically to individual needs (also known as 'personalised medicine').

Given the benefits, there are many biobanks that have been established across the globe - European Biobanks, North American Biobanks, Asian Biobanks, Australian Biobanks, and Middle East Biobanks. Some of the notably largest biobanks in the world store samples collected from half a million of individuals or more, such as the UK Biobank, "All of Us" Biobank in the US, and Shanghai Zhangjiang Biobank.

In order to leverage on the collected samples to accelerate and further increase laboratory discoveries, some biobanks create network between them. Such approach would facilitate collaboration among local and foreign researchers, as well as enable flow of information and knowledge between the networks. For instance, the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) was created in 2008

to bring all existing biobanks in Europe together to make high quality biological resources available for human health research across the continent.

Biobanking in Malaysia

Malaysia also plays an important role in this global effort to combat human health issues by establishing its own national biobank known as The Malaysian Cohort Project. It is an initiative by the government in 2005, set up through the then Ministry of Science, Technology and Innovation (MOSTI), coordinated by the Malaysian Genome Institute and led by the UKM Medical Molecular Biology Institute (UMBI). It is part of the Asia Cohort Consortium, a network of population-based biobanks across the Asian jurisdictions namely Bangladesh, China, India, Japan, Korea, Mongolia, Singapore, and Taiwan. Primarily, the Project aims to improve the approach taken in preventing as well as to improve the treatment and diagnosis of major diseases that have been identified in Malaysia.

In so doing, more than 100,000 participants aged between 35 and 65 from various socioeconomic groups from all over the country were recruited. This can be considered as the biggest and most comprehensive cohort study in Malaysia, storing the largest number of human samples in the country, thus providing valuable resource for epidemiological and biomedical research.

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Aside from the Malaysian Cohort Project, Malaysia has a number of Assisted Reproductive Technology (ART) clinics that can be considered as biobanks. Based on the data published by the Malaysian Society for Assisted Reproductive Technology, there are 17 ART clinics in the country that provide treatment and carry out research as well as storage program donors for sperm, eggs and embryos. In addition, a general search on Google map indicates that there are 19 other ART clinics in Malaysia.

There are also tissue-specific-based biobanks that store certain types of human tissues (i.e. blood) in Malaysia such as Cellsafe International (Malaysia) Sdn. Bhd., Cryocord Sdn. Bhd., and StemLife Berhad. University of Malaya itself has also established a number of biobanks to store specific tissues such as the Malaysian Periodontal Database and Biobank System and Malaysian Oral Cancer Database and Tissue Bank System.

Ethical and Legal Issues of Biobanking

Notwithstanding the promising benefits, there is a myriad of complex ethical and legal issues surrounding this area, some of which are briefly discussed here.

First, there is an issue relating to the privacy and confidentiality of personal information and data linked to the samples collected (associated data). There are concerns that there may be misuse of personal information and associated data, as this could also be used to trace the individual's family genetic information and private life. Any misconduct and mishandling of the data could have an adverse effect on this field and impact on public trust.

Second, as human subjects are involved, informed consent is an essential tool to ensure ethical conduct and to protect them. Its application has been debated extensively in terms of which model of consent (i.e. broad consent, specific consent, meta-consent, dynamic consent) would be appropriate and it is still yet to be resolved.

Third, there is an issue about ownership of the samples and data collected. A survey shows that even though most sample donors believed that research institutions are the owners of the samples collected, they indicated that they have the right to decide what would be done to their donated samples. This could pose a problem when samples are shared and transferred to another institution. How would the 'custodian' biobanks know exactly what happen to the transferred samples?

Fourth, there are also issues with commercial activities such as commercialisation of biobanks resources (samples and data) or products derived from research using the resources, private investment in public biobanks, or private funding of biobanks. Previous studies have shown that public trust in biobanks and biobank research decreases significantly if commercial actors are involved. Samples donor also expressed concern of the possibility of losing control over their samples if research work involved for-profit companies. Also, researchers may gain personal recognition and financial benefits through commercialisation, which could violate the interests of research participants.

Due to the abovementioned ethical issues, many countries have introduced rules to regulate biobanks and they vary from one country to another. A recent study has shown that different biobanks adopt different regulatory approaches, for instance, accessibility policies and such regulatory environment can be viewed as the greatest barrier to collaboration and sample sharing, undermining the acceleration of scientific discoveries. Therefore, international scholars have been discussing the need to harmonise and standardise regulation of biobanking at the global level. This is particularly vital to facilitate samples and data sharing between individual biobanks.

Biobank Governance in Malaysia

Currently, Malaysia has yet to introduce specific legislation to govern biobanking. However, there are relevant laws such as the existing Private Healthcare Facilities and Services Act 1998 and Human Tissue Act 1974 which function as umbrella Acts for all healthcare services and facilities in the country. Therefore, ART clinics that function as biobanks fall within the ambit of these Acts. The Ministry of Health has published Standards for Assisted Reproductive Technology (ART) Facility in 2012 and the National Committee for Clinical Research has introduced Guidelines on the Use of Human Biological Tissues for Research 2006. These documents act merely as guidelines and therefore, not legally binding. It highlights the requirement of informed consent, whereby it requires a written and signed consent form for any ART procedures and a separate consent form for procedures other than treatment such as cryopreservation and subsequent use of the surplus embryos and gametes.

The Personal Data Protection Act 2010 is also relevant given the fact that the collected samples and reproductive materials contain sensitive information that can be traced back to the individuals. The only regulatory document that was established specifically for biobanking would be the National Standard for Cord Blood Banking and Transplantation 2008, as the name implies. Another relevant guidelines is the National Guidelines for Stem Cell Research and Therapy 2009 that regulate the use of human embryos for research purposes as well as gametes or blastocyst donation.

Despite the existing regulations, it is arguable that Malaysia needs to revisit its regulatory framework for biobanking to ensure not only that its approach is in line with the international regulation, but also to safeguard local samples. This is particularly important given the fact that Malaysian's biggest biobank is part of an international network. It has been argued by scholars that low- and middle-income countries have weaker research capacity and governance mechanisms for biobanks than that of high-income countries. High-income countries may see the advantage of using human samples from low- and middle-income countries that are rich with genetic diversity. This will place low- and middle-income countries at a risk of exploitation especially if it concerns benefit sharing.

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Since Malaysia falls within the category of low- and middle-income countries, it would be interesting to find out Malaysia's current situation as to whether or not Malaysia would need to develop a more robust regulatory framework. In addition, it can also be argued that it would be beneficial to have specific legislation and clear regulatory regime in place to facilitate ethical development of biobanking in Malaysia. In so doing, further research is needed since currently, there is a lack of literature on the ethical issues from the local perspective as well as the examination of the adequacy of the current framework.

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Dr Mohammad Firdaus bin Abdul Aziz obtained his BSc (Genetics and Molecular Biology) from the University of Malaya. He was awarded the National Science Fellowship and furthered his studies at the University of Sheffield, where he graduated with MA in Biotechnological Law and Ethics. Firdaus then pursued his doctorate at the University of Oxford. His doctoral research was on improvement to the regulatory framework for human stem cell research in Malaysia. He is also interested in exploring ethical and legal issues of other emerging technologies.